UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,420	11/29/2001	Stephen J. Benkovic	00-387-J	2558

20306 7590 05/20/2004

MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP
300 S. WACKER DRIVE
32ND FLOOR
CHICAGO, IL 60606

EXAMINER	
TRAN, MY CHAU T	
ART UNIT	**PAPER NUMBER**
1639	

DATE MAILED: 05/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/996,420	BENKOVIC ET AL.	
	Examiner	Art Unit	
	MY-CHAU T TRAN	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 January 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-9* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2, drawn to a compound, classified in class 536, subclass 7.3.

II. Claim 3, drawn to a pharmaceutical composition, classified in class 424, subclass 657.

III. Claims 4-5, drawn to a method for the treatment of a disease or disorder with a therapeutically effective amount of a compound, classified in class 514, subclass 64.

IV. Claims 6-7, drawn to a method for the treatment of a disease or disorder with a therapeutically effective amount of the pharmaceutical composition, classified in class 514, subclass 885.

V. Claim 8, drawn to combinatorial library, classified in class 435, subclass 5.

VI. Claim 9, drawn to a packaged pharmaceutical, classified in class 435, subclass 810.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of Groups I, II, V, and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the different inventions are structurally different (e.g. the pharmaceutical composition require a pharmaceutically acceptable carrier or a combinatorial

library comprises a plurality of 'structurally' different compounds) and would have different functions and different effects.

3. Inventions of Groups III, and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the different inventions as claimed have different method steps that have different functions and modes of operation that is requiring different reagents and/or producing different products/results.

The method step of administering a therapeutically effective amount of a compound to a patient of Group III is not required by the claims of Group IV. The method step of administering a therapeutically effective amount of a pharmaceutical composition to a patient of Group IV is not required by the claims of Group III.

4. Inventions of Group I (product) and Group III (process) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product such an immunoassay or antigen-antibody binding. This restriction requirement is also applicable with the product of Groups II, V, and VI.

5. Inventions of Group I (product) and Group IV (process) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product such a method of identifying of a target in a sample or antigen-antibody binding. This restriction requirement is also applicable with the product of Groups II, V, and VI.

6. Because these inventions are distinct for the reasons given above and the searches required are not co-extensive thus requiring a burdensome search, restriction for examination purposes as indicated is proper. Additionally, different patentability considerations are involved for each group. For example, a patentability determination for Group II would involve a determination of the patentability of the combination of a composition comprised of a compound and a pharmaceutical carrier (independent of its use) while a patentability determination for Group IV would involve a consideration of the patentability of a method for the treatment of a disease or disorder with a therapeutically effective amount of the pharmaceutical composition. These considerations are very different in nature.

Even though some of the groups are classified in the same class/subclass, this has no effect on the non-patent literature search. Different groups would require completely different searches in non-patent databases, and there is no exception that the searches would be co-extensive.

7. This application contains claims directed to the following patentably distinct species of the claimed invention:

8. ***If applicants elect the invention of Group I***, applicants are required to further elect a **single** specific compound from the various compounds disclosed in the specification on page 6-7 and Example I.

The species are distinct, each from the other, because each species have different chemical structure and/or physiochemical properties and would be capable of separate manufacture and/or use; and would necessitate different and separately burdensome manual and computer bibliographic and structure searches in both patent and non-patent areas.

For this response to be complete and for search purposes, applicants should provide the chemical structure of elected compounds or composition or species, wherein each specific formula substituents of each of the above identified elected species are defined either by picture, or by expressing the species in terms of the variables of the formula.

9. ***If applicants elect the invention of Group II***, applicants are required to further elect a **single** specific pharmaceutical composition (i.e. a **single** specific compound from the various compounds disclosed in the specification on page 6-7 and Example I and a pharmaceutical carrier).

The species are distinct, each from the other, because each species have different chemical structure and/or physiochemical properties and would be capable of separate manufacture and/or use; and would necessitate different and separately burdensome manual and computer bibliographic and structure searches in both patent and non-patent areas.

For this response to be complete and for search purposes, applicants should provide the chemical structure of elected compounds or composition or species, wherein each specific formula substituents of each of the above identified elected species are defined either by picture, or by expressing the species in terms of the variables of the formula.

10. ***If applicants elect the invention of Group III***, applicants are required to further elect a **single** specific compound from the various compounds disclosed in the specification on page 6-7 and Example I.

The species are distinct, each from the other, because each species have different chemical structure and/or physiochemical properties and would be capable of separate manufacture and/or use; and would necessitate different and separately burdensome manual and computer bibliographic and structure searches in both patent and non-patent areas.

For this response to be complete and for search purposes, applicants should provide the chemical structure of elected compounds or composition or species, wherein each specific formula substituents of each of the above identified elected species are defined either by picture, or by expressing the species in terms of the variables of the formula.

11. ***If applicants elect the invention of Group IV***, applicants are required to further elect a **single** specific pharmaceutical composition (i.e. a **single** specific compound from the various compounds disclosed in the specification on page 6-7 and Example I and a pharmaceutical carrier).

The species are distinct, each from the other, because each species have different chemical structure and/or physiochemical properties and would be capable of separate manufacture and/or use; and would necessitate different and separately burdensome manual and computer bibliographic and structure searches in both patent and non-patent areas.

For this response to be complete and for search purposes, applicants should provide the chemical structure of elected compounds or composition or species, wherein each specific formula substituents of each of the above identified elected species are defined either by picture, or by expressing the species in terms of the variables of the formula.

12. ***If applicants elect the invention of Group V***, applicants are required to further elect a **single** specific compound from the various compounds disclosed in the specification on page 6-7 and Example I.

The species are distinct, each from the other, because each species have different chemical structure and/or physiochemical properties and would be capable of separate manufacture and/or use; and would necessitate different and separately burdensome manual and computer bibliographic and structure searches in both patent and non-patent areas.

For this response to be complete and for search purposes, applicants should provide the chemical structure of elected compounds or composition or species, wherein each specific formula substituents of each of the above identified elected species are defined either by picture, or by expressing the species in terms of the variables of the formula.

13. ***If applicants elect the invention of Group VI***, applicants are required to further elect a **single** specific pharmaceutical composition (i.e. a **single** specific compound from the various compounds disclosed in the specification on page 6-7 and Example I and a pharmaceutical carrier).

The species are distinct, each from the other, because each species have different chemical structure and/or physiochemical properties and would be capable of separate manufacture and/or use; and would necessitate different and separately burdensome manual and computer bibliographic and structure searches in both patent and non-patent areas.

For this response to be complete and for search purposes, applicants should provide the chemical structure of elected compounds or composition or species, wherein each specific formula substituents of each of the above identified elected species are defined either by picture, or by expressing the species in terms of the variables of the formula.

14. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and ***a listing of all claims readable thereon, including any claims subsequently added***. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

15. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

16. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

17. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

18. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MY-CHAU T TRAN whose telephone number is 571-272-0810.

The examiner can normally be reached on Mon.: 8:00-2:30; Tues.-Thurs.: 7:30-5:00; Fri.: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANDREW WANG can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct
May 19, 2004

PADMASHRI PONNALURI
PRIMARY EXAMINER